UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA
Civil No.

UNITED STATES OF AMERICA,	)
	)
Plaintiff,	)
	)
v.	)
	)
SYBARITIC, INC., a corporation, ANTHONY S. DAFFER, STEVEN J. DAFFER, and RONALD BERGLUND, individuals,	)
	)
Defendants.	)
_____	)

COMPLAINT FOR PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, respectfully represents to this Court as follows:

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), to enjoin Sybaritic, Inc. ("Sybaritic"), a corporation, and Anthony S. Daffer, Steven J. Daffer, and Ronald Berglund, individuals (hereafter collectively, "Defendants"), from violating:

A. 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, or causing the introduction or delivery for introduction into interstate commerce, articles of devices, as defined by 21 U.S.C. §

321(h), that are adulterated within the meaning of the Act as follows:

1. 21 U.S.C. § 351(h), in that the methods used in, or the facilities or controls use for, their manufacture, packing, storage, and installation are not in conformity with current good manufacturing practice requirements prescribed at 21 C.F.R. Part 820; and

2. 21 U.S.C. § 351(f)(1)(B), in that they are Class III devices pursuant to 21 U.S.C. § 360c(f), and there are no approved applications for premarket approval ("PMAs") on file with the United States Food and Drug Administration ("FDA") as required by 21 U.S.C. § 360e(a), and the devices do not have an approved application for an investigational device exemption under 21 U.S.C. § 360j(g).

B. 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, or causing the introduction or delivery for introduction into interstate commerce, articles of devices, as defined by 21 U.S.C. § 321(h), that are misbranded within the meaning of the Act as follows:

1. 21 U.S.C. § 352(t)(2), in that Defendants fail to furnish material or information respecting certain devices

to FDA as required by 21 U.S.C. § 360(i) and the implementing regulations set forth in 21 C.F.R. Part 803; and

2. 21 U.S.C. § 352(o), in that Defendants fail to provide notice or other information respecting certain devices to FDA as required by 21 U.S.C. § 360(k).

C. 21 U.S.C. § 331(k), by causing devices to become adulterated within the meaning of 21 U.S.C. §§ 351(h) and/or 351(f)(1)(B), as described in paragraph A above, and misbranded within the meaning of 21 U.S.C. §§ 352(t)(2) and/or 352(o), as described in paragraph B above, while such devices are held for sale after shipment in interstate commerce; and

D. 21 U.S.C. § 331(q)(1)(B), in that Defendants fail to furnish notification or other material or information to FDA as required by 21 U.S.C. § 360(i) and the implementing regulations set forth in 21 C.F.R. Part 803.

JURISDICTION AND VENUE

2. This Court has jurisdiction pursuant to 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331 and 1345.

3. Venue in this District is proper pursuant to 28 U.S.C. § 1391(b) and (c).

DEFENDANTS

4. Defendant Sybaritic is incorporated under the laws

of South Dakota. Sybaritic designs, manufactures, and/or distributes articles of device, within the meaning of 21 U.S.C. § 321(h), at its facility located at 9220 James Avenue South, Bloomington, Minnesota. Specifically, Sybaritic is a manufacturer, specification developer, and/or distributor of various medical devices used in the laser surgery, dermatological, and spa industry.

5. Steven J. Daffer is the Owner and Chairman of Sybaritic. Steven Daffer is responsible for the overall direction of the firm, and also specifically oversees the firm's product development, product management, and international relations and sales. He reports to Anthony Daffer with respect to these particular departments. He performs his duties at 9220 James Avenue South, Bloomington, Minnesota.

6. Anthony S. Daffer is the Chief Executive Officer (CEO) of Sybaritic. Anthony Daffer is responsible for, and has had authority over, all of the firm's daily operations including sales, regulatory affairs, and product development. Although he is the CEO, Anthony Daffer defers to Steve Daffer on issues regarding the overall direction of the firm. Anthony Daffer performs his duties at 9220 James Avenue South,

Bloomington, Minnesota.

7. Ronald Berglund is Sybaritic's Product Manager. Mr. Berglund is significantly involved in the firm's premarket notification submissions and negotiations with FDA regarding such submissions. He reports directly to Anthony Daffer, and performs his duties at 9220 James Avenue South, Bloomington, Minnesota.

DEFENDANTS' DEVICES

8. Defendants have been, and are now, manufacturing and distributing in interstate commerce various articles of devices, as defined by 21 U.S.C. § 321(h), including, but not limited to the following: moist steam cabinets (Dermalife), intense pulsed light systems (NannoLight MP50), surgical laser instruments (SkinClear SRVH; LaserPeel Trimatrixx), microdermabrasion systems (SkinBella), and ultrasound and non-invasive subdermal therapy systems (Dermosonic).

9. Defendants products are devices, within the meaning of 21 U.S.C. § 321(h), in that they make claims in their promotional materials and on their website that their products are intended (a) for the use in the cure, mitigation, treatment, or prevention of disease, and/or (b) to affect the structure or any function of the body of man.

10. With respect to certain of these devices (e.g. SlimLine), Sybaritic designs, manufactures, and distributes the device itself. With respect to others (e.g. Dermalife, NannoLight MP50, SkinClear SRVH, Dermosonic), Defendants design the device and then contract with foreign companies to manufacture it according to Sybaritic's specifications. The foreign manufacturers ship Defendants' devices from outside the state of Minnesota, and Defendants then distribute these devices nationally and internationally.

11. Defendants' devices have been classified as Class III devices by statute, 21 U.S.C. § 360c(f), because they are intended for human use, were not introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, and do not meet the exemptions set forth in 21 U.S.C. § 360c(f)(1).

LEGAL STANDARDS

12. A device must be manufactured, packed, stored, and installed in conformity with good manufacturing practice to ensure its safety and effectiveness. 21 U.S.C. § 360j(f). The statutory good manufacturing practice requirement is set out in the quality system ("QS") regulation for devices, 21 C.F.R. Part 820. A device that has been manufactured, packed,

stored, or installed in violation of this requirement is deemed to be adulterated. 21 U.S.C. § 351(h).

13. A Class III device is adulterated if: (1) it is required to have in effect an approved application for PMA under 21 U.S.C. § 360e(a); (2) there is no FDA-approved PMA application in effect; and (3) it is not exempt from premarket approval as an investigational device under 21 U.S.C. § 360j(g). 21 U.S.C. § 351(f)(1)(B).

14. Virtually all devices introduced or delivered for introduction into interstate commerce for commercial distribution after May 28, 1976, are automatically classified as Class III as a matter of law, 21 U.S.C. § 360c(f)(1), and, with certain exceptions, must have an approved application for PMA prior to marketing. 21 U.S.C. §§ 360c(f)(1), 360e(a). The sponsor of a device may avoid this automatic statutory Class III designation, and thereby avoid the PMA process, only if it obtains an order from FDA reclassifying the device into Class I or Class II, or an order finding that the device is "substantially equivalent" to a legally-marketed predicate device that does not require premarket approval (commonly known as a "cleared 510(k) premarket notification submission" or "510(k)"). 21 U.S.C. §§ 360c(f), 360e(a) and (b), 360(k).

15. Premarket notification is required for any device that is: (a) being introduced into commercial distribution for the first time (21 C.F.R. § 807.81(a)(1)); (b) currently in commercial distribution, but is significantly changed or modified in design, components, or methods of manufacture such that the change could significantly affect the safety or effectiveness of the device (21 C.F.R. § 807.81(a)(3)(i)); or (c) currently in commercial distribution, but has a significant change or modification in its intended use (21 C.F.R. § 807.81(a)(3)(ii)).

16. The introduction or delivery for introduction into interstate commerce of an adulterated article of device is a violation of the Act, 21 U.S.C. § 331(a).

17. Under the Act, every manufacturer of a device intended for human use must submit certain reports and other information to FDA "as the Secretary may by regulation reasonably require to assure that the device is not adulterated or misbranded and to otherwise assure its safety and effectiveness." 21 U.S.C. § 360(i).

18. Every manufacturer is required to submit a medical device report ("MDR") to FDA within 30 days of receiving or otherwise becoming aware of information that reasonably

suggests that their marketed device may have caused or contributed to a death or serious injury, and to conduct an adequate investigation into MDR reportable events. 21 C.F.R. §§ 803.50(a), 803.50(b)(3).

19. A device is misbranded, pursuant to 21 U.S.C. § 352(t)(2), if a device manufacturer fails or refuses to submit to FDA MDRs as required by 21 CFR Part 803.

20. Under the Act, the device is misbranded if a person who is required to register pursuant to 21 U.S.C. § 360 and proposes to introduce a device into interstate commerce for commercial distribution fails to submit to FDA a premarket notification submission. 21 U.S.C. § 352(o).

21. The introduction or delivery for introduction into interstate commerce of a misbranded article of device is a violation of the Act, 21 U.S.C. § 331(a).

22. The adulteration and misbranding of a device while it is held for sale after shipment in interstate commerce constitutes a violation of the Act, 21 U.S.C. § 331(k).

23. The failure or refusal to furnish any notification or other material or information required under 21 U.S.C. § 360(i), and its implementing regulations at 21 C.F.R. Part 803, is a violation of the Act, 21 U.S.C. § 331(q)(1).

MARCH 2009 INSPECTIONS

24. FDA inspected Sybaritic on March 3-18 and again on 26-30, 2009. These inspections revealed numerous violations of the Act and its implementing regulations, including Defendants' distribution of adulterated and misbranded devices. Specifically, the FDA investigators documented the following violations with respect to one of more of Defendants' devices:

A. Defendants fail to comply with the QS regulation set forth in 21 C.F.R. Part 820, as follows:

1. Defendants fail to establish and maintain adequate procedures to ensure the identification, documentation, evaluation, and segregation of nonconforming products or to document the disposition of nonconforming products, including the justification for the use of nonconforming products and the signature of the individual(s) authorizing the products' use, as required by 21 C.F.R. § 820.90(a), (b)(1);

2. Defendants fail to establish and maintain adequate procedures to fully analyze sources of quality data to identify existing and potential causes of nonconforming products, or other quality problems, nor do they employ

appropriate statistical methodology where necessary to detect recurring quality problems, as required by 21 C.F.R. § 820.100(a)(1);

3. Defendants fail to establish and maintain adequate procedures to identify, document, validate, or, where appropriate, verify, review, and approve design changes before implementation, as required by 21 C.F.R. § 820.30(i);

4. Defendants fail to establish and maintain adequate procedures to ensure that all purchased or received products and services conform to specified requirements, as required by 21 C.F.R. § 820.50(a); and

5. Defendants fail to establish and maintain adequate procedures to ensure adequate acceptance activities are performed, as required by 21 C.F.R. § 820.80(a).

B. Defendants are distributing Class III devices, under 21 U.S.C. § 360c(f), for which they do not have an approved application for PMA pursuant to 21 U.S.C. § 360e(a) or a cleared 510(k) pursuant to 21 U.S.C. § 360(k), nor do they have an approved application for an investigational device exemption under 21 U.S.C. § 360j(g).

1. Defendants do not have an approved application for PMA or cleared 510(k) for their microdermabrasion system,

SkinBella, which they are introducing into commercial distribution for the first time, as required by 21 C.F.R. § 807.81(a)(1). 2. There is a cleared 510(k) for Defendants' pulsed light and laser system, NannoLight MP50. Defendants have changed the devices' design and energy source in such a way that the changes could significantly affect the devices' safety or effectiveness, but have not received FDA approval of a PMA application for the modified device nor obtained clearance of a 510(k) for the modified device, as required by 21 C.F.R. § 807.81(a)(3)(i). Further, Defendants are making claims for the NannoLight MP50 that are not cleared in the 510(k) and constitute a major change or modification in the device's intended use, but have not received FDA approval of a PMA application for the currently marketed device nor obtained clearance of a 510(k) for the new intended uses for the device, as required by 21 C.F.R. § 807.81(a)(3)(ii).

3. There is a cleared 510(k) for Defendants' long pulsed laser, SkinClear SRVH. Defendants are making claims for the device that are not cleared in the 510(k) and constitute a major change or modification in the device's intended use, but have not received FDA approval of a PMA application for the currently marketed device nor obtained

clearance of a 510(k) for the new intended uses for the device, as required by 21 C.F.R. § 807.81(a)(3)(ii).

4. Defendants have a cleared 510(k) for their an ultrasound and non-invasive subdermal therapy system device, Dermosonic. Defendants have changed the devices' design in such a way that the changes could significantly affect the devices' safety or effectiveness, but have not received FDA approval of a PMA application for the modified device nor obtained clearance of a 510(k) for the modified device, as required by 21 C.F.R. § 807.81(a)(3)(i). Further, Defendants are making claims for the device that are not cleared in the 510(k) and constitute a major change or modification in the device's intended use, but have not received FDA approval of a PMA application for the currently marketed device nor obtained clearance of a 510(k) for the new intended uses for the device, as required by 21 C.F.R. § 807.81(a)(3)(ii).

5. There is a cleared 510(k) for Defendants' Dermalife Family of Devices (including Hydration Station, Spa Oceana, Spa Jet, and Spa Fengshui), all of which are moist steam cabinets. Defendants have changed the Hydration Station's design in such a way that the changes could significantly affect the device's safety or effectiveness, but

have not received FDA approval of a PMA application for the modified device nor obtained clearance of a 510(k) for the modified device, as required by 21 C.F.R. § 807.81(a)(3)(i). Further, Defendants are making claims for this device that are not cleared in the 510(k) and constitute a major change or modification in the device's intended use, but have not received FDA approval of a PMA application for the currently marketed device nor obtained clearance of a 510(k) for the new intended uses for the device, as required by 21 C.F.R. § 807.81(a)(3)(ii).

C. Defendants failed to comply with the regulations regarding the submission of MDRs set forth at 21 C.F.R. Part 803. Specifically, Defendants fail to: (a) submit an MDR within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that their marketed device may have caused or contributed to a serious injury, as required by 21 C.F.R. § 803.50(a)(1); and (b) conduct an adequate investigation into MDR reportable events, as required by 21 C.F.R. § 803.50(b)(3).

25. At the conclusion of both the March 2009 inspections, FDA investigators issued a List of Inspectional Observations ("Form FDA 483") to Steven Daffer or Anthony

Daffer, detailing Defendants' violations of the Act and discussed the documented observations with the recipient.

PRIOR INSPECTIONS

26. FDA previously inspected Sybaritic three times between 2004 and 2008 as follows: May/June 2004, April/May 2005, and February/April 2008. During each of these inspections, FDA investigators observed numerous violations the QS regulation the same as or similar to those described in paragraph 24.A., including but not limited to, violations involving the following: design controls (21 C.F.R. § 820.30); complaint handing (21 C.F.R. § 820.198); acceptance activities (21 C.F.R. § 820.80); corrective and preventative action (21 C.F.R. § 820.100); nonconforming products (21 C.F.R. § 820.90); production and process controls (21 C.F.R. § 820.70); purchasing controls (21 C.F.R. § 820.50); quality audits (21 C.F.R. § 820.22); and document controls (21 C.F.R. § 820.40).

27. In addition to numerous QS violations, FDA investigators documented during the 2008 inspection that Defendants were manufacturing and distributing thirteen devices without premarket approval or clearance; failed to document their decision-making processes regarding whether to

file MDRs for numerous burn injury complaints; and failed to report to FDA a field correction made to their devices, which had been initiated to address complaints of burns.

28. At the conclusion of each of the prior inspections, the FDA investigators issued a Form FDA 483 detailing Defendants' violations of the Act to the most responsible person at the firm and discussed the documented observations with the recipient.

29. Defendants have been and are violating 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, or causing the introduction or delivery for introduction into interstate commerce, articles of devices that are adulterated within the meaning of 21 U.S.C. §§ 351(h) and 351(f)(1)(B), as set forth above.

30. Defendants have been and are violating 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, or causing the introduction or delivery for introduction into interstate commerce, articles of devices that are misbranded within the meaning of 21 U.S.C. §§ 352(t)(2) and 352(o), as set forth above.

31. Defendants have been and are violating 21 U.S.C. § 331(k), by causing the devices to become adulterated within

the meaning of 21 U.S.C. §§ 351(h) and 351(f)(1)(b), and misbranded within the meaning of 21 U.S.C. §§ 352(t)(2) and 352(o), while such devices are held for sale after shipment in interstate commerce, as set forth above.

32. Defendants have been and are violating 21 U.S.C. § 331(q)(1)(B), by failing to furnish notification or other material or information to FDA as required by 21 U.S.C. § 360(i) and the implementing regulations, 21 C.F.R. Part 803, as set forth above.

PRIOR NOTICE OF VIOLATIONS

33. Defendants are well aware that their practices violate the Act. FDA has repeatedly warned Defendants, both orally and in writing, about their violative conduct, and has emphasized the importance of Defendants' compliance with the Act.

34. FDA issued Defendant Stephen Daffer a Letter of Non-Compliance, dated March 15, 1994, based on its review of promotional brochures for two Sybaritic products. FDA notified Defendants that, because these brochures contained claims that caused these products to be medical devices, Sybaritic was required to obtain premarket approval or clearance for them and the devices' manufacture and

distribution must be conducted pursuant to current good manufacturing practice.

35. In 1999 and 2001, FDA issued Warning Letters to Defendant Steven Daffer, stating that Defendants did not have premarket approval for a number of devices, causing the devices to be adulterated and misbranded within the meaning of the Act, 21 U.S.C. §§ 351(f)(1)(B) and 352(o).

36. Following FDA's 2004 inspection of Sybaritic, FDA issued another Warning Letter to Defendant Steven Daffer on September 1, 2004, notifying him that Defendants' devices (spa systems, microdermabrasion products, and massage systems) were: (a) adulterated under 21 U.S.C. § 351(h), in that they are not manufactured in conformity with good manufacturing practice to ensure their safety and effectiveness; and (b) misbranded under 21 U.S.C. § 352(t)(2), in that the firm failed to establish and maintain MDR procedure as required by 21 C.F.R. Part 803. All of FDA's Warning Letters notified Defendants that failure to correct the cited deviations could result in further action including injunction.

37. On September 21, 2004, FDA met with representatives of Sybaritic to discuss FDA's ongoing concerns regarding the firm's marketing of devices without premarket approval,

promoting devices with unapproved claims, and QS deficiencies.

38. At the conclusion of each of FDA's inspections of the firm, the FDA investigators issued a Form FDA 483 detailing Defendants' various violations of the Act to the most responsible individual at the firm, and discussed the documented observations with the recipient.

39. Despite numerous warnings from FDA over the past five years and Defendants' promises to correct the numerous ongoing violations, Defendants continue to violate the Act, as observed in FDA's most recent inspections.

40. Based on Defendants' conduct, Plaintiff believes that, unless restrained by order of this Court, Defendants will continue to violate 21 U.S.C. §§ 331(a), (k), and (q).

WHEREFORE, Plaintiff prays:

I. That Defendants and each of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, be permanently restrained and enjoined pursuant to 21 U.S.C. § 332(a) from directly or indirectly:

A. violating 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, or

causing the introduction or delivery for introduction into interstate commerce, any article of device that is adulterated within the meaning of 21 U.S.C. §§ 351(h) or 351(f)(1)(B), or misbranded within the meaning of 21 U.S.C. §§ 352(t)(2) or 352(o);

B. violating 21 U.S.C. § 331(k), by causing any article of device to become adulterated within the meaning of 21 U.S.C. §§ 351(h) or 351(f)(1)(B), and misbranded within the meaning of 21 U.S.C. §§ 352(t)(2) or 352(o), while such article is held for sale after shipment in interstate commerce; and

C. violating 21 U.S.C. § 331(q)(1)(B), by failing to furnish notification or other material or information required by 21 U.S.C. § 360(i).

II. That the Court order Defendants and each of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, to cease directly or indirectly manufacturing, packing, labeling, and distributing (domestically and internationally) any device, unless and until:

A. Defendants' methods, facilities, and controls used

to manufacture, process, pack, label, hold, and distribute devices are established, operated, and administered in compliance with 21 U.S.C. § 360j(f)(1) and the Quality System regulation prescribed in 21 C.F.R. Part 820, and in a manner that has been found acceptable to FDA; and

B. Defendants ensure that, for each model of device designed, manufactured, and distributed, they have obtained premarket approval or clearance from FDA and that the device is designed, manufactured, and distributed in accordance with such approval or clearance.

III. That the Court authorize FDA, pursuant to this injunction, to inspect Defendants' place of business to ensure continuing compliance with the terms of this injunction, with the costs of such inspections to be born by Defendants at the rates prevailing at the time the inspections are performed.

IV. That Plaintiff be granted judgment for its costs herein, and that this Court grant such other and further relief as it deems just and proper.

SIGNATURE PAGE TO FOLLOW

Respectfully submitted,

TONY WEST
Assistant Attorney General

B. TODD JONES
December 22, 2009 United States Attorney

s/Friedrich A. P. Siekert
FRIEDRICH A.P. SIEKERT
Assistant United States Attorney
MN Attorney ID No.142013

s/Friedrich A. P. Siekert
for GERALD KELL
Senior Trial Counsel
Office of Consumer Litigation
Department of Justice
Civil Division
P.O. Box 386
Washington, D.C. 20044
(202) 514-1586

OF COUNSEL:
DAVID S. CADE
Acting General Counsel

MICHAEL M. LANDA
Acting Chief Counsel
Food and Drug Administration

ERIC M. BLUMBERG
Deputy Chief Counsel, Litigation

MICHELE LEE SVONKIN
Associate Chief Counsel for Enforcement
United States Department of
Health and Human Services
Food and Drug Administration
Office of the General Counsel
5600 Fishers Lane, GCF-1
Rockville, MD 20857
(301) 827-2803